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Quality Orthopaedic Instruments and Implants

Enclosure D - 510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.93.

The Polarus AF Rod is an intramedullary rod which addresses tibiocalcaneal arthrodesis procedures (ankle fusions). The rod's dimensions are 11 mm x 150 mm and it is interlocked in place by 4.5 mm cortical screws.

The Polarus AF Rod is manufactured from 6AL/4V ELI per ASTM F 136. This device is provided pre-sterile. Sterility is achieved by gamma radiation. Validation of sterility is maintained on site. Sterility level is 10^{-6} . Information regarding implantation, packaging, and labeling have been provided.

The Polarus AF Rod is similar to Smith & Nephew Richards, Inc.'s Intramedullary Rod in design, function, indications and surgical technique and is expected to perform as well as similar devices.